

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Brian Eugene Baldwin et al.

Serial No.: 09/928,007

Filed: August 10, 2001

Confirmation No.: 6430

Atty. File No.: 50012-00004

For: METHOD, SYSTEM, AND APPARATUS  
FOR HANDLING, LABELING, FILLING  
AND CAPPING SYRINGES

) Group Art Unit: 3721

) Examiner: Brian D. Nash

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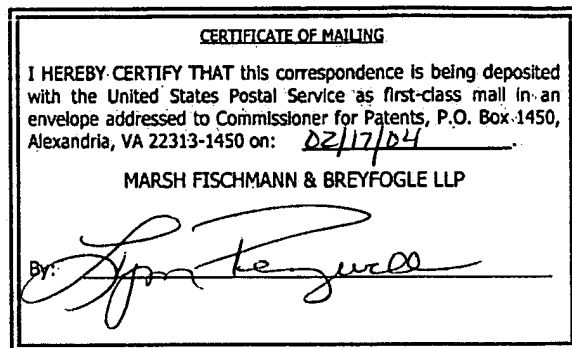
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**DECLARATION UNDER 37 CFR §1.132**  
**OF RANDALL W. SMITH**

I, **Randall W. Smith**, state:

1. That I received a Bachelor of Science degree in Mechanical Engineering from Brigham Young University in 1983.

2. That I have 20 years of work experience in connection with the design and production of medical products, including the following positions:

a. Mechanical Engineer, Becton/Dickinson Advanced Diagnostic Systems, a provider of various medical products, including automated immunoassay instruments, 1983 to 1987;

b. Senior Engineer, Project and Research and Development Manager and Team Leader, Cobe Laboratories, Inc., a provider of various medical products, including dialysis products, 1987 to 1998;

c. Senior Engineer, Vice President of New Product Engineering and Vice President of Technology, Baxa Corporation, a provider of syringes for oral liquid medications and intravenous drug administration, and automated systems for the preparation and administration of fluid medications, 1998 to Present.

3. That based on the foregoing, I believe I have at least ordinary skill in the field of medical products for fluid medication administration.

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4. That I have reviewed and understand the specification and pending independent Claims 1, 92 and 102 of the above-identified patent application, said Claims 1, 92, 102 each being directed to an apparatus adapted for automated handling, comprising (i) a plurality of syringe bodies each including a barrel having a dispensing end and opposing end, a plunger slidably disposed in the opposing end, and a cap removably disposed on the dispensing end, wherein a clean, contained volume is defined within the barrel, and (ii) a flexible belt attached to the barrels of the syringe bodies, wherein the syringe bodies are disposable in a predetermined orientation with at least one end of each barrel being accessible; a copy of pending Claims 1, 92 and 102 being attached hereto as Appendix A ("Pending Claims 1, 92 and 102").

5. That, in my opinion, at the time of invention of Pending Claims 1, 92 and 102, it was a problem in the field of medical products for fluid administration to efficiently provide and maintain a clean, contained volume in a syringe body in automated handling processes for a plurality of syringe bodies ("Problem").

6. That, in my opinion, the invention of Pending Claims 1, 92 and 102 addresses said Problem by providing an apparatus comprising a plurality of capped syringe bodies having clean, contained volumes and being interconnected by a flexible belt.

7. That, on information and belief, at the time of invention of Pending Claims 1, 92 and 102, it was not known in the field of medical products for fluid medication administration to utilize an apparatus comprising a plurality of capped syringe bodies having clean, contained volumes and being interconnected by a flexible belt, as specified in Pending Claim 1, 92 and 102.

8. That I have reviewed U.S. Patent No. 3,823,818 to Shaw ("Shaw").

9. That, based on my review, Shaw is directed to thermoplastic container blow-molding (e.g. bottles) utilizing unfinished, open-ended preforms, and (i) fails to disclose or suggest an apparatus comprising a plurality of capped syringe bodies having clean, contained volumes and being interconnected by a flexible belt, (ii) fails to disclose or suggest any applicability of the teachings thereof to the field of medical products, including products for fluid medication administration, (iii) fails to address or recognize the Problem, and (iv) fails to

disclose or suggest any apparatus comprising preforms or other vessels having a clean, contained volume.

10. That, in my opinion, as of the time of invention of Pending Claims 1, 92, 102, and due at least in part to the differences and shortcomings identified in Paragraph 9 above, Shaw does not render obvious the invention of Pending Claims 1, 92 and 102.

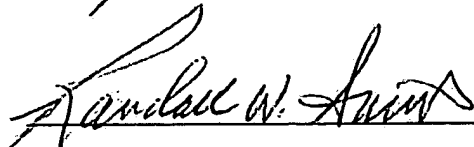
11. That I have reviewed U.S. Patent No. 5,884,457 to Ortiz et al. ("Ortiz et al.").

12. That based on my review, Ortiz et al. is directed to a method and apparatus in which non-interconnected delivery devices are filled by individual positioning of non-interconnected delivery devices in a non-flexible feeding magazine of a filling machine for movement along a predetermined feeding path of the filling machine, and (i) fails to disclose or suggest an apparatus having a flexible belt interconnected to a plurality of capped syringe bodies having clean, contained volumes, and (ii) fails to recognize any need or provide any motivation for interconnecting a flexible belt to a plurality of capped syringe bodies.

13. That, in my opinion, as of the time of invention of Pending Claims 1, 92 and 102, and due at least in part to the differences and shortcomings identified in Paragraphs 9 and 12 above, Shaw and Ortiz are not combinable to render obvious the invention of Pending Claims 1, 92 and 102.

I HEREBY DECLARE THAT all statements made herein, of my own knowledge, are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful, false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

DATED this 13<sup>th</sup> day of February, 2004.

  
Randall W. Smith

**APPENDIX A**

Pending Claims 1, 92 and 102 of U.S. Patent Application No. 09/928,007, filed August 10, 2001, entitled "METHOD, SYSTEM, AND APPARATUS FOR HANDLING, LABELING, FILLING AND CAPPING SYRINGES"

1. An apparatus adapted for automated handling, comprising:

a plurality of syringe bodies, each comprising a barrel having a dispensing end and an opposing end, a plunger slidably disposed in the opposing end of the barrel, and a cap removably disposed on the dispensing end of the barrel, wherein a clean, contained volume is defined within said barrel between the plunger and the cap ; and,

a flexible belt fixedly attached to each said barrel of said plurality of syringe bodies, wherein said plurality of syringe bodies are positionable in a predetermined orientation and at least one said dispensing end and said opposing end of each said barrel of said plurality of syringe bodies is accessible.

92. An apparatus adapted for automated handling, comprising:

a plurality of syringe bodies each comprising a barrel having a dispensing end and an opposing end, a cap removably and replacably disposed on the dispensing end of the barrel, and a plunger slidably disposed in the opposing end of the barrel, wherein for each of said plurality of syringe bodies a clean, contained volume is defined within said barrel between the plunger and cap, and

a flexible belt fixedly attached to each said barrel of said plurality of syringe bodies, wherein said plurality of syringe bodies are positionable in a predetermined orientation and at least one end of each said barrel of said plurality of syringe bodies is accessible, wherein said belt is of a predetermined length between adjacent ones of said plurality of syringe bodies, said predetermined length being sufficient to define label flaps upon severance of the belt between said adjacent ones of the plurality of syringe bodies, and wherein at least one surface of each said predetermined length of said belt is adapted for providing contents-related information thereon.

102. An apparatus adapted for automated handling, comprising:

a plurality of syringe bodies each comprising a barrel having a dispensing end and an opposing end, a cap removably and replacably disposed on the dispensing end of the barrel, and

a plunger slidably disposed in the opposing end of the barrel, wherein a clean, contained volume is defined within the barrel between the plunger and the cap; and

a flexible belt fixedly attached to each said barrel of said plurality of syringe bodies, wherein said plurality of syringe bodies are positionable in a predetermined orientation and at least one end of each said barrel of said plurality of syringe bodies is accessible, and wherein said belt comprises opposing layers adjoined in face-to-face relation between adjacent ones of said plurality of syringe bodies and wrapped about opposing sides of the barrels of each of said plurality of syringe bodies.



5. That I have reviewed and understand the above-identified patent application, including pending independent Claims 1, 92 and 102, a copy of which is attached hereto as Appendix A, and that I believe that one or more of the pending independent claims 1, 92 and 102 cover belted syringe body products marketed by Assignee since April of 2002 (collectively "Covered Products").

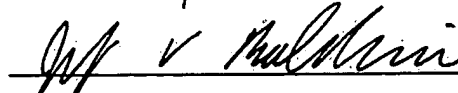
6. That at least 2,268,200 Covered Products have been sold by Assignee since April of 2002, generating total gross revenues of over \$728,000.00 to Assignee.

7. That during the period from April of 2002 to present, the ratio of the above-noted gross revenues generated by sales of the Covered Products in relation to the total amount of funds expended by Assignee on advertising and promotion of the Covered Products is significantly greater than analogous ratios for other medical products for fluid medication administration of which I am aware.

8. That, in my opinion, the commercial success of the Covered Products noted above is due, in significant part, to the combination of features set forth in one or more of the pending independent Claims 1, 92 and 102 of the above-identified application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

DATED this 13<sup>th</sup> day of February, 2004.

  
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Jeffrey V. Baldwin

**APPENDIX A**

Pending Claims 1, 92 and 102 of U.S. Patent Application No. 09/928,007, filed August 10, 2001, entitled "METHOD, SYSTEM, AND APPARATUS FOR HANDLING, LABELING, FILLING AND CAPPING SYRINGES"

1. An apparatus adapted for automated handling, comprising:

a plurality of syringe bodies, each comprising a barrel having a dispensing end and an opposing end, a plunger slidably disposed in the opposing end of the barrel, and a cap removably disposed on the dispensing end of the barrel, wherein a clean, contained volume is defined within said barrel between the plunger and the cap ; and,

a flexible belt fixedly attached to each said barrel of said plurality of syringe bodies, wherein said plurality of syringe bodies are positionable in a predetermined orientation and at least one said dispensing end and said opposing end of each said barrel of said plurality of syringe bodies is accessible.

92. An apparatus adapted for automated handling, comprising:

a plurality of syringe bodies each comprising a barrel having a dispensing end and an opposing end, a cap removably and replacably disposed on the dispensing end of the barrel, and a plunger slidably disposed in the opposing end of the barrel, wherein for each of said plurality of syringe bodies a clean, contained volume is defined within said barrel between the plunger and cap, and

a flexible belt fixedly attached to each said barrel of said plurality of syringe bodies, wherein said plurality of syringe bodies are positionable in a predetermined orientation and at least one end of each said barrel of said plurality of syringe bodies is accessible, wherein said belt is of a predetermined length between adjacent ones of said plurality of syringe bodies, said predetermined length being sufficient to define label flaps upon severance of the belt between said adjacent ones of the plurality of syringe bodies, and wherein at least one surface of each said predetermined length of said belt is adapted for providing contents-related information thereon.

102. An apparatus adapted for automated handling, comprising:

a plurality of syringe bodies each comprising a barrel having a dispensing end and an opposing end, a cap removably and replacably disposed on the dispensing end of the barrel, and



a plunger slidably disposed in the opposing end of the barrel, wherein a clean, contained volume is defined within the barrel between the plunger and the cap; and

a flexible belt fixedly attached to each said barrel of said plurality of syringe bodies, wherein said plurality of syringe bodies are positionable in a predetermined orientation and at least one end of each said barrel of said plurality of syringe bodies is accessible, and wherein said belt comprises opposing layers adjoined in face-to-face relation between adjacent ones of said plurality of syringe bodies and wrapped about opposing sides of the barrels of each of said plurality of syringe bodies.



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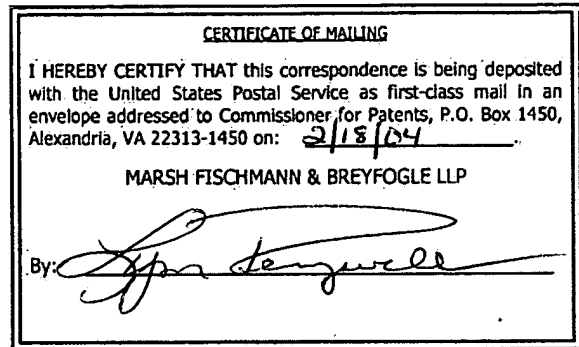
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For: METHOD, SYSTEM, AND APPARATUS  
FOR HANDLING, LABELING, FILLING  
AND CAPPING SYRINGES

) Group Art Unit: 3721

) Examiner: Brian D. Nash



DECLARATION UNDER 37 CFR §1.132 OF BRIAN E. BALDWIN **RECEIVED**

I, **Brian E. Baldwin**, state:

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1. That I received a Bachelor of Science degree in Mechanical Engineering and a Master of Science Degree in Industrial Engineering from Northwestern University, in 1954 and 1955 respectively. TECHNOLOGY CENTER R3700

2. That I have had 46 years of work experience in connection with the design and production of medical products for fluid medication administration, including the following positions:

a. Product Development Engineer, American Hospital Supply Corp., a provider of various medical products including hypodermic syringes and needles, 1956 to 1958.

b. Founder and President of Manufacturing, Process Laboratories, Inc., a provider of hypodermic needles and prefilled syringes, 1958 to 1974; and

c. Founder and President, Baxa Corporation, a provider of syringes for oral liquid medications and intravenous drug administration, and automated systems for the preparation and administration of fluid medications, 1975 to 1997.

3. That based on the foregoing, I believe I have at least ordinary skill in the field of medical products for fluid medication administration.

4. That I have reviewed and understand the specification and pending independent Claims 1, 92 and 102 of the above-identified patent application, said Claims 1, 92, 102 each being directed to an apparatus adapted for automated handling, comprising (i) a plurality of syringe bodies each including a barrel having a dispensing end and opposing end, a plunger slidably disposed in the opposing end, and a cap removably disposed on the dispensing end, wherein a clean, contained volume is defined within the barrel, and (ii) a flexible belt attached to the barrels of the syringe bodies, wherein the syringe bodies are disposable in a predetermined orientation with at least one end of each barrel being accessible; a copy of pending Claims 1, 92 and 102 being attached hereto as Appendix A ("Pending Claims 1, 92 and 102").

5. That, in my opinion, at the time of invention of Pending Claims 1, 92 and 102, it was a problem in the field of medical products for fluid administration to efficiently provide and maintain a clean, contained volume in a syringe body in automated handling processes for a plurality of syringe bodies ("Problem").

6. That, in my opinion, the invention of Pending Claims 1, 92 and 102 addresses said Problem by providing an apparatus comprising a plurality of capped syringe bodies having clean, contained volumes and being interconnected by a flexible belt.

7. That, on information and belief, at the time of invention of Pending Claims 1, 92 and 102, it was not known in the field of medical products for fluid medication administration to utilize an apparatus comprising a plurality of capped syringe bodies having clean, contained volumes and being interconnected by a flexible belt, as specified in Pending Claim 1, 92 and 102.

8. That I have reviewed U.S. Patent No. 3,823,818 to Shaw ("Shaw").

9. That, based on my review, Shaw is directed to thermoplastic container blow-molding (e.g. bottles) utilizing unfinished, open-ended preforms, and (i) fails to disclose or suggest an apparatus comprising a plurality of capped syringe bodies having clean, contained volumes and being interconnected by a flexible belt, (ii) fails to disclose or suggest any applicability of the teachings thereof to the field of medical products, including products for fluid medication administration, (iii) fails to address or recognize the Problem, and (iv) fails to

disclose or suggest any apparatus comprising preforms or other vessels having a clean, contained volume.

10. That, in my opinion, as of the time of invention of Pending Claims 1, 92, 102, and due at least in part to the differences and shortcomings identified in Paragraph 9 above, Shaw does not render obvious the invention of Pending Claims 1, 92 and 102.

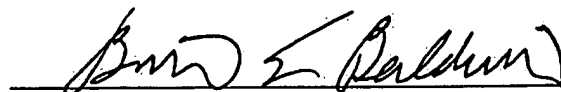
11. That I have reviewed U.S. Patent No. 5,884,457 to Ortiz et al. ("Ortiz et al.").

12. That based on my review, Ortiz et al. is directed to a method and apparatus in which non-interconnected delivery devices are filled by individual positioning of non-interconnected delivery devices in a non-flexible feeding magazine of a filling machine for movement along a predetermined feeding path of the filling machine, and (i) fails to disclose or suggest an apparatus having a flexible belt interconnected to a plurality of capped syringe bodies having clean, contained volumes, and (ii) fails to recognize any need or provide any motivation for interconnecting a flexible belt to a plurality of capped syringe bodies.

13. That, in my opinion, as of the time of invention of Pending Claims 1, 92 and 102, and due at least in part to the differences and shortcomings identified in Paragraphs 9 and 12 above, Shaw and Ortiz are not combinable to render obvious the invention of Pending Claims 1, 92 and 102.

I HEREBY DECLARE THAT all statements made herein, of my own knowledge, are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful, false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

DATED this 18<sup>th</sup> day of February, 2004.



Brian E. Baldwin

**APPENDIX A**

**Pending Claims 1, 92 and 102 of U.S. Patent Application No. 09/928,007, filed August 10, 2001, entitled "METHOD, SYSTEM, AND APPARATUS FOR HANDLING, LABELING, FILLING AND CAPPING SYRINGES"**

1. An apparatus adapted for automated handling, comprising:

a plurality of syringe bodies, each comprising a barrel having a dispensing end and an opposing end, a plunger slidably disposed in the opposing end of the barrel, and a cap removably disposed on the dispensing end of the barrel, wherein a clean, contained volume is defined within said barrel between the plunger and the cap ; and,

a flexible belt fixedly attached to each said barrel of said plurality of syringe bodies, wherein said plurality of syringe bodies are positionable in a predetermined orientation and at least one said dispensing end and said opposing end of each said barrel of said plurality of syringe bodies is accessible.

92. An apparatus adapted for automated handling, comprising:

a plurality of syringe bodies each comprising a barrel having a dispensing end and an opposing end, a cap removably and replacably disposed on the dispensing end of the barrel, and a plunger slidably disposed in the opposing end of the barrel, wherein for each of said plurality of syringe bodies a clean, contained volume is defined within said barrel between the plunger and cap, and

a flexible belt fixedly attached to each said barrel of said plurality of syringe bodies, wherein said plurality of syringe bodies are positionable in a predetermined orientation and at least one end of each said barrel of said plurality of syringe bodies is accessible, wherein said belt is of a predetermined length between adjacent ones of said plurality of syringe bodies, said predetermined length being sufficient to define label flaps upon severance of the belt between said adjacent ones of the plurality of syringe bodies, and wherein at least one surface of each said predetermined length of said belt is adapted for providing contents-related information thereon.

102. An apparatus adapted for automated handling, comprising:

a plurality of syringe bodies each comprising a barrel having a dispensing end and an opposing end, a cap removably and replacably disposed on the dispensing end of the barrel, and a plunger slidably disposed in the opposing end of the barrel, wherein a clean, contained volume is defined within the barrel between the plunger and the cap; and

a flexible belt fixedly attached to each said barrel of said plurality of syringe bodies, wherein said plurality of syringe bodies are positionable in a predetermined orientation and at least one end of each said barrel of said plurality of syringe bodies is accessible, and wherein said belt comprises opposing layers adjoined in face-to-face relation between adjacent ones of said plurality of syringe bodies and wrapped about opposing sides of the barrels of each of said plurality of syringe bodies.